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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

AFREMOVA, V

ART UNIT

PAPER NUMBER

1651

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/443,842

Applicant(s)

Toner et al.

Examiner

Vera Afremova

Group Art Unit

1651

☒ Responsive to communication(s) filed on Nov 17, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-36 are pending and under examination.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-36 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of prior U.S. Patent No. US 6,127,177. This is a double patenting rejection.

Claim Objections

Claim 14 is objected to under 37CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim 14 is believed to depend on claim 13 rather than claim 11 as written.

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Claim Rejections - 35 U.S.C. § 112

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 13, 23 and 33 are rendered indefinite by confusing step b which is directed a procedure of loading cells with preservation agent to a predetermined intracellular concentration. The indented procedure seems to be a mixing of the porated cells with preservation agent at particular concentration for successful preservation of viable biological material. The exemplified procedure appear to be a mixing step wherein an equilibrium between intracellular and extracellular concentrations of the preservation agent is reached (pp.13-14) . And a "predetermined" concentration is expressed as a concentration of a solution added to porated cells (pp.21-22). Thus, the invention as claimed fails to point out towards steps which applicants regard as the invention. With regard to concentration claims 6, 7, 16, 17, 28, 29, 35 and 38 are rendered indefinite by recitation about intracellular concentration.

Claims 4 and 26 are rendered indefinite by the use of phrase "substantially" in relation to non-permeating properties of agent. And claim 22 is rendered indefinite by the recitation of temperature being "ambient". The claims as written do not clearly set forth the metes and bounds of the patent protection desired.

Claim 18 fails to further limit because sugar is the only bio-protective agent of the method of claim 16.

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Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,4,5-7, 10-13, rejected under 35 U.S.C. 102(b) as being anticipated by US 5,242,792.

Claims are directed to a method for preserving biological material by steps of porating membranes of biological material, treating with bio-protecting agent, submitting the treated biological material to drying or freeze-drying or freezing and recovering preserved viable biological material with undamaged membrane. Some claims are further drawn to preservation agents such as trehalose, sucrose and etc., and its concentration less than 0.4 M.

US 5,242,792 discloses a method for preserving biological material by steps of porating membranes of biological material, treating with bio-protecting agent, submitting the treated biological material to drying or freeze-drying or freezing and recovering preserved viable biological material with undamaged membrane. (See Fig.1; col.4, lines 15-25 or lines 50-64). The procedure comprises step of mixing biological material with two agents wherein one is a permeabilizing agent or porating agent and second is protective agent such as trehalose, sucrose and etc. The permeabilizing agent is regarded as a porating agent because it cause cell membrane to became more permeable or introduce pores (col.3, lines 55-60). The patent teaches steps of

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recovering biological material and reversing membrane poration by the disclosure of rehydration in a high humidity chamber , for example (see col. 4, line 60). The concentration of preservation agent is less than 0.4 M (example 1). The cited patent anticipates the claimed invention because it discloses an identical method for preserving biological material which comprises substantially similar or identical steps as claimed and as intended.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,242,792 taken with US 5,425,951, McGann et al., US 5,827,741, Russo et al. and Russo M.

Claims are directed to a method for preserving biological material by steps of porating membranes of biological material, treating with preservation agents and submitting to drying or freeze-drying or freezing treated biological material. Some claims are further drawn to porating procedure using *Staphylococcus aureus* H5 alpha toxin. Some claims are further drawn to preservation agents such as trehalose, sucrose and etc. Some claims are directed to biological material such as mammalian nucleated cells, fibroblasts, islets of Langerhans and etc.

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US 5,242,792 is relied here as explained above. It lacks the disclosure of *Staphylococcus aureus* H5 alpha toxin as a permeabilizing agent or a porating agent and the disclosure of particular mammalian cells as biological material in the method for preserving biological material.

US 5,425,951 discloses a method for preserving biological material which encompasses the use of two agents.

McGann et al. discloses a method for preserving biological material such as for example: fibroblasts, lymphocytes, granulocytes (abstract). The reference teaches a practical implication for preservation protocols such as the use of two modes or agents which actions are directed to reduction of osmotic stress and stabilization of membrane (p.184, col.2, par.2).

US 5,827,741 discloses a method for preserving biological material such as for example: islets of Langerhans. The method encompasses the use of two agents.

Russo et al. teaches a permeabilizing agent such as *Staphylococcus aureus* H5 alpha toxin, and a procedure for reversing cell membrane.

Russo M. suggests the use of *Staphylococcus aureus* H5 alpha toxin for manipulating cell permeability during cryopreservation (pp.69-70).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute a permeabilizing agent *Staphylococcus aureus* H5 alpha toxin taught by Russo et al. for permeabilizing agents of US 5,425,951, McGann et al. or US 5,827,741 as suggested by Russo M. in order to practice the method for preserving biological material as claimed with a reasonable expectation of success in recovering viable cells because the

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use of two modes or two agents in the successful preservation procedure as taught and recommended by the prior art references and the use of *Staphylococcus aureus* H5 alpha toxin offers the ability to control membrane permeabilization as taught by Russo et al. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

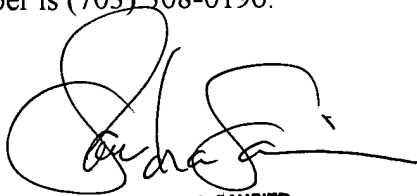
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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January 26, 2001.



SANDRA E. SAUCIER
PRIMARY EXAMINER